## Remarks

Claims 3, 4 and 15 remain pending in this application. Applicants request that the Examiner consider the following remarks.

**Rejections under 35 U.S.C. § 103 (a)**

The Examiner has rejected claims 3, 4 and 15 under 35 U.S.C. § 103 (a) as obvious in light of the combination of Lane et al. (1995) and Finkelstein et al. (1998). The Lane reference describes that intermittent human PTH administration at doses of 40 μg/kg or 400 μg/kg increases trabecular bone volume in ovariectimized, **estrogen deficient**, osteopenic rats. Finkelstein et al. describe that administration of 40 μg of human parathyroid hormone fragment (1-34) by subcutaneous injection prevents bone loss in women with GnRH analog-induced **estrogen deficiency**.

The pending claims are limited to the use of parathyroid hormone to prevent bone loss or stimulate bone formation in a host that is currently being treated with one or more glucocorticoid compounds or experiencing adverse bone effects resulting from contact with one or more glucocorticoid compounds, representing patients that are experiencing **glucocorticoid-induced bone loss.**

The Examiner states that "the claims are directed to a method of increasing the lifespan of osteoblasts in a bone-containing host in need of preventing bone loss or stimulating bone formation by administering at least 10 μg per kilogram body weight of parathyroid hormone fragment". The Examiner does not emphasize the limitation that the host is currently being treated with one or more

glucocorticoid compounds or experiencing adverse bone effects resulting from contact with one or more glucocorticoid compounds.

Osteoporosis is classified into two major categories: primary and secondary. Primary osteoporosis refers to osteoporosis that is caused by hormone loss (primarily estrogen loss after menopause) or normal aging. Secondary osteoporosis is not related to normal aging or hormone loss; secondary osteoporosis is caused by disease or medication, such as endocrine-related diseases, bone marrow disorders, malnutrition, chemotherapy and glucocorticoid treatment. It has generally be found that treatment of secondary osteoporosis is more complex than treatment of primary osteoporosis and it is largely dependant on the underlying disease.

The pending claims are limited to treatment of one type of secondary osteoporosis--**glucocorticoid-induced osteoporosis**. Applicants have made the surprising discovery that PTH prevents glucocorticoid-induced apoptosis of osteoblastic and osteoclastic cells thereby providing a treatment to reduce the adverse effects of glucocorticoids on bone in hosts undergoing glucocorticoid therapy. In contrast, the teachings of Lane et al and Finkelstein et al are directed solely to primary osteoporosis due to estrogen deficiency. Both references teach the prevention of **estrogen-deficient bone loss** with PTH. Further, neither reference even mentions the potential impact of their study on pateints with secondary osteoporosis. Thus, there is no suggestion or motivation for one skilled in the art to apply the teachings of Lane and Finkelstein to patients with glucocorticoid-induced osteoporosis. In addition, since primary and secondary osteoporosis are recognized as separate categories of osteoporosis with different etiologies and clinical manifestations, one skilled in the art would not find it obvious to apply the teachings of Lane and Finkelstein to a distinct disease state.

## Conclusion

In light of the comments presented herein, Applicants request that the Examiner allow all pending claims.

Respectfully submitted,

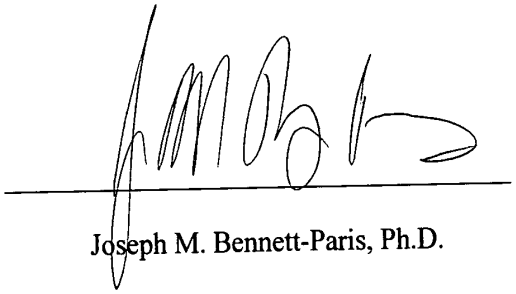
Stephanie D. Adams, Ph.D.

Reg. No. 47,378

King & Spalding
191 Peachtree St.
Atlanta, Georgia 30303
404-572-3404
404-572-5145 (fax)

CERTIFICATE OF MAILING (37 CFR 1.8a)

I hereby certify that this Response to Office Action, along with any paper referred to as being attached or enclosed, is being deposited with the United States Postal Service on the date shown below with sufficient postage as first-class mail in an envelope addressed to the Commissioner for Patents, Washington, D.C. 20231.



Joseph M. Bennett-Paris, Ph.D.

February 18, 2003